ALLEGRA-D ALLERGY AND CONGESTION- fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release Chattem, Inc.

Allegra-D Allergy and Congestion 24 HR

Drug Facts

Active ingredients

(in each extended-release tablet)

Fexofenadine HCl 180 mg

Purpose

Antihistamine

Active ingredients

(in each extended-release tablet)

Pseudoephedrine HCl 240 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI)
 (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2
 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an
 MAOI, ask a doctor or pharmacist before taking this product.
- If you have difficulty swallowing

Ask a doctor before use if you have

- heart disease
- thyroid disease
- glaucoma
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- kidney disease. Your doctor should determine if you need a different dose.

When using this product

- do not take more than directed
- do not take at the same time as aluminum or magnesium antacids
- do not take with fruit juices (see Directions)
- the tablet coating may be seen in the stool (this is normal). Continue to take as directed (see Directions).

Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve within 7 days or are accompanied by a fever
- you get nervous, dizzy, or sleepless

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

• do not divide, crush, chew or dissolve the tablet; swallow tablet whole

adulte and children I / Moare	take 1 tablet with a glass of water every 24 hours on an empty stomach; do not take more than 1 tablet in 24 hours
children under 12 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information

- each tablet contains: **sodium 33 mg**
- safety sealed: do not use if carton is opened or if individual blister units are torn or opened
- store between 20° and 25°C (68° and 77°F)

Inactive ingredients

acetone, black iron oxide, cellulose acetate, colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1 aluminum lake, glycerol triacetate, hypromellose, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, polyethylene glycol, propylene glycol, povidone, sodium chloride, talc, titanium dioxide, water

Questions or comments?

call toll-free **1-800-633-1610** or www.allegra.com

PRINCIPAL DISPLAY PANEL

NDC 41167-4320-7 NON-DROWSY Allegra-D[®] ALLERGY & CONGESTION fexofenadine HCl 180 mg/antihistamine pseudoephedrine HCl 240 mg/nasal decongestant Extended Release Tablets 15 Tablets



ALLEGRA-D ALLERGY AND CONGESTION

fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-4320	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FEXO FENADINE HYDRO CHLO RIDE (UNII: 2S068B75ZU) (FEXO FENADINE - UNII: E6582LO H6 V)	FEXOFENADINE HYDROCHLORIDE	180 mg	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	240 mg	

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
TRIACETIN (UNII: XHX3C3X673)	
ACETONE (UNII: 1364PS73AF)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PO VIDO NE (UNII: FZ989 GH94E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND	Size	19 mm	
Flavor		Imprint Code	308;AV	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-4320-3	1 in 1 CARTON	03/03/2011	03/01/2019
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-4320-5	2 in 1 CARTON	03/03/2011	
2		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41167-4320-7	3 in 1 CARTON	03/03/2011	
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021704	03/03/2011	

Labeler - Chattem, Inc. (003336013)

Revised: 12/2020 Chattem, Inc.